UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NANCY L. BUC,
MADHUSHA DISSANAYAKE, and
BUC & BEARDSLEY, LLP,

Plaintiffs,

v.

FOOD AND DRUG ADMINISTRATION,

Defendant.

Civil Action No. 10-00293 (CKK)

MEMORANDUM OPINION
(February 1, 2011)
(Amended February 24, 2011)

This action arises out of a series of requests made by the law firm Buc & Beardsley, LLP ("Buc & Beardsley") and two of its attorneys, Nancy L. Buc and Madhusha Dissanayake (collectively, "Plaintiffs"), pursuant to the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552 *et seq.*, seeking the disclosure of documents and records relating to Zicam cold remedy nasal products from the Food and Drug Administration (the "FDA"), an operating division of the United States Department of Health and Human Services. After the FDA failed to fully respond to several separate FOIA requests within the statutorily prescribed time period, Plaintiffs commenced this action seeking declaratory and injunctive relief, including an order requiring the FDA to promptly produce the records and documents requested. Presently before the Court is the FDA's [7] Motion for a Stay pursuant to *Open America v. Watergate Special Prosecution Force*, 547 F.2d 605 (D.C. Cir. 1976). Specifically, the FDA seeks a stay of the proceedings in this action until early September 2011—seventeen months and two weeks from the filing of its

moving papers[1]—in order to complete its review and release the records responsive to Plaintiffs' various requests. For the reasons set forth below, the Court concludes that the FDA has failed to carry its burden of establishing the "exceptional circumstances" required to justify the stay it seeks and shall therefore DENY the FDA's [7] Motion for a Stay. While mindful of the substantial backlog of pending FOIA requests that the FDA presently faces, in light of the FDA's failure to establish its right to the relief sought and the fact that the FDA has already taken for itself a period of time far in excess of the statutory default to discharge of its obligations, the Court shall require the FDA to (a) begin processing Plaintiffs' outstanding requests immediately, (b) promptly produce any responsive documents on a rolling basis, and (c) complete its production on or before March 4, 2011.

I. BACKGROUND

Plaintiff Buc & Beardsley, LLP represents Matrixx Initiatives, Inc. ("Matrixx") in FDA-related matters and submitted the FOIA requests at issue in this action on Matrixx's behalf. Compl., Docket No. [1], ¶ 4. Each of the five FOIA requests at issue was signed either by Plaintiff Nancy L. Buc, a partner at Buc & Beardsley, or by Plaintiff Madhusha Dissanayake, an associate at the firm. *Id.* ¶¶ 12, 20, 28, 34, 42. The five requests, in chronological order of their submission date, are as follows:

- **Request 2009-5323:** On June 29, 2009, Plaintiffs submitted their first

[1] The FDA filed the present Motion for a Stay on March 22, 2010. *See* Def.'s Mot. for a Stay, Docket No. [7]. Plaintiffs filed an opposition on April 5, 2010. *See* Pls.' Opp'n to Def.'s Mot. for a Stay, Docket No. [8]. The FDA filed a reply on April 12, 2010. *See* Def.'s Reply in Supp. of Mot. for a Stay ("Def.'s Reply"), Docket No. [9]. The parties have filed a variety of supporting papers relating to this motion. For purposes of economy, the Court shall not cite to those documents here, but notes that it renders its decision today upon the parties' submissions, the attachments thereto, and the record as a whole.

FOIA request to the FDA ("Request 2009-5323"), requesting the FDA's health hazard evaluations of Zicam cold remedy nasal products. *Id.* ¶¶ 11-17.

- **Request 2009-6862:** On August 18, 2009, Plaintiffs submitted their second FOIA request to the FDA ("Request 2009-6862"), requesting documents and records relating to Compliance Policy Guide 7132.15. *Id.* ¶¶ 19-25.

- **Request 2009-8794:** On October 22, 2009, Plaintiffs submitted their third FOIA request to the FDA ("Request 2009-8794"), requesting documents and records relating to a Drug Safety Oversight Board Meeting discussing Zicam cold remedy nasal products. *Id.* ¶¶ 27-31.

- **Request 2009-9403:** On November 16, 2009, Plaintiffs submitted their fourth FOIA request to the FDA ("Request 2009-9403"), requesting "all documents or records . . . relating to a press conference FDA held regarding Zicam cold remedy nasal products, a Warning Letter issued by FDA to Matrixx, regarding these products, and a News Release, Public Health Advisory, Fact Sheet, Consumer Article, and Drug Safety Podcast that FDA posted on its website." *Id.* ¶¶ 33-39.

- **Request 2009-9424:** Also on November 16, 2009, Plaintiffs submitted their fifth and final FOIA request to the FDA ("Request 2009-9424"), requesting "documents and records relating to the statements of Douglas C. Throckmorton, M.D. that were made during a telephone call with counsel for Matrixx from Buc & Beardsley." *Id.* ¶¶ 41-47.

The timeliness of the FDA's response to two of these five requests is no longer at issue in this action. First, the FDA responded in full to Request 2009-8794 four months after its receipt and prior to the commencement of this action. *Id.* ¶ 31. Second, in the time since this action was commenced, the FDA has apparently responded in full to Request 2009-5323—albeit over eight months after its receipt. Decl. of Frederick J. Sadler in Supp. of Def.'s Mot. for a Stay ("Sadler Decl."), Docket No. [7-1], ¶ 16; Decl. of Nancy B. Sager in Supp. of Def.'s Mot. for a

Stay ("Sager Decl."), Docket No. [7-15], ¶ 34.[2] As a result, the only requests that remain outstanding in full or in part are Request 2009-6862, Request 2009-9403, and Request 2009-9424 (collectively, the "Outstanding Requests"). As of today, two of these requests have been pending for approximately one year and two months, while the remaining request has been pending for approximately one year and five months.

Each of the Outstanding Requests was forwarded to the FDA's Center for Drug Evaluation and Research (the "CDER") and thereafter routed to the CDER's Division of Information Disclosure Policy (the "DIDP") for further processing. Sager Decl. ¶¶ 36, 40, 44.[3] In processing FOIA requests, the DIDP employs a multi-track system: (1) requests are assigned to the "Simple Track" when they (a) "can be answered quickly with readily available documents" and "require no further searching or redacting," or (b) are "reasonably expected by DIDP to require no more than one hour of search time and two hours of review time;" and (2) requests that do not qualify for the "Simple Track," because they will require more extensive searches or significant review time, are generally assigned to the slower "Complex Track." *Id.* ¶ 8. The pending searches pertaining to the Outstanding Requests have all been assigned to the DIDP's

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[2] In this context, "[a]gency affidavits are accorded a presumption of good faith, which cannot be rebutted by purely speculative claims." *SafeCard Servs., Inc. v. Secs. & Exch. Comm'n,* 926 F.2d 1197, 1200 (D.C. Cir. 1991) (internal quotation marks omitted). In any event, Plaintiffs have, for the most part, accepted as true the facts averred in the FDA's declarations and instead targeted their arguments towards what conclusions may reasonably be drawn from those facts.

[3] While other component parts of the FDA were also tasked with searching for records responsive to Plaintiffs' various requests, those component parts have already completed their search and have produced responsive documents. *See, e.g.*, Sadler Decl. ¶¶ 16, 22, 42. At this point, the only records that are yet to be searched are in the CDER's custody and are set to be processed by the DIDP. Accordingly, in addressing the present motion, the parties have appropriately focused their attention on the CDER and the DIDP.

Complex Track. *Id.* ¶¶ 37, 41, 46.[4]

Regardless of whether they are on the Simple or Complex Track, the DIDP generally processes requests on a "first-in, first-out" basis. *Id.* ¶ 8. An exception to this policy is made when a request that is low in the Complex Track queue seeks identical or very similar records to another request that has reached the top of the queue. *Id.* ¶ 10. In that situation, in the course of processing the request at the top of the queue, the DIDP may, in the interest of efficiency, release the overlapping records to parties who are further back in the queue. *Id.* In this case, the DIDP has determined that there is substantial overlap between Request 2009-9403 and Request 2009-9424 and an earlier, third-party request for Zicam-related documents in the Complex Track. *Id.* ¶¶ 43, 46. Therefore, the DIDP intends to process Plaintiffs' Request 2009-9403 and Request 2009-9424 once the previously filed Zicam-related request reaches the top of the Complex Track queue. *Id.*

On January 5, 2011, the FDA was directed to advise the Court of its progress in responding to Plaintiffs' Outstanding Requests. Min. Order (Jan. 5, 2011). On January 19, 2011, the FDA filed a status report with the Court, which provides the most recent picture of the status of Plaintiffs' requests. *See* Def.'s Status Report, Docket No. [10]. The status of each of the Outstanding Request is as follows:

- **Request 2009-6862:** As of January 19, 2011, there were approximately 562 requests ahead of Plaintiffs' Request 2009-6862 in the DIDP's

[4] The DIDP also maintains a third track—the "Drug Safety Queue"—for "[a]ll requests for individual safety reports of drug adverse events." Sager Decl. ¶ 9. In this case, the DIDP determined that a portion of Request 2009-9403 pertained to individual safety reports for drug adverse events and, as such, was assigned to the Drug Safety Queue and has since been processed. *Id.* ¶¶ 41-42. The remainder of Request 2009-9403 was assigned to the Complex Track and remains outstanding. *Id.* ¶¶ 41, 43.

Complex Track queue. *Id.* at 2. The FDA estimates that the request would reach the top of the queue in approximately eight months, take approximately two weeks to process, and be completed in or about early September 2011. *Id.*

- **Request 2009-9403 and Request 2009-9424:** As of January 19, 2011, there were approximately 451 requests ahead of the third-party FOIA request that overlaps with Plaintiffs' Request 2009-9403 and Request 2009-9424 in the DIDP's Complex Track queue. *Id.* at 3. The FDA estimates that the request should reach the top of the queue in approximately five months, take approximately one month thereafter to process, and be completed in mid- to late-July 2011. *Id.*

Should the requested stay be granted, by the time of the anticipated productions, Request 2009-9403 and 2009-9242 will have been outstanding for over one year and seven months; Request 2009-6862 will have been outstanding for over two years.

II. LEGAL STANDARD

Within twenty working days of receipt, an agency must determine whether to comply with a request for records and notify the requester of its determination. 5 U.S.C. § 552(a)(6)(A)(i). Where, as here, the agency fails to respond within the designated time limit, the requester "shall be deemed to have exhausted his administrative remedies," and may commence an action in district court seeking the prompt production of the records requested. *Id.* § 552(a)(6)(C)(i). Nevertheless, Congress has provided a limited "safety valve" for agencies that are unable to comply with these strict time limitations. *Open Am. v. Watergate Special Prosecution Force*, 547 F.2d 605, 610 (D.C. Cir. 1976). Where the agency "can show exceptional circumstances exist and that [it] is exercising due diligence in responding to the request, the court may . . . allow the agency additional time to complete its review of the records." 5 U.S.C. § 552(a)(6)(C)(i). By its terms, this "safety valve"—commonly referred to as an "*Open America* stay" in reference to the decision from the United States Court of Appeals for

the District of Columbia Circuit that first articulated its scope—involves two separate elements: "exceptional circumstances;" and "due diligence." *Id.*

To establish "exceptional circumstances," the agency must show both (a) that it is "deluged with [a] volume of requests . . . vastly in excess of that anticipated by Congress," and (b) that "existing resources are inadequate to deal with [the] volume of such requests within the [statutorily prescribed] time limits." *Open Am.*, 547 F.2d at 616. Various circumstances outside the raw volume of outstanding requests may be relevant to the determination as to whether "exceptional circumstances" exist in a given case, including: (a) an agency's efforts to reduce the number of pending requests; (b) the existence and amount of classified material; (c) the size and complexity of other requests processed by the agency; (d) the resources being devoted to the declassification of classified material of public interest; and (e) the number of requests for records by courts or administrative tribunals. *Gov't Accountability Project v. U.S. Dep't of Health & Human Servs.*, 568 F. Supp. 2d 55, 59 (D.D.C. 2008). Critically, however, the term "exceptional circumstances" is expressly defined to generally exclude "delay[s] that result[] from a predictable agency workload of requests." 5 U.S.C. § 552(a)(6)(C)(ii); *see also Leadership Conference on Civil Rights v. Gonzales*, 404 F. Supp. 2d 246, 259 n.4 (D.D.C. 2005) ("An agency must show more than a great number of requests to establish[ ] exceptional circumstances under the FOIA."). If an agency can show no more than a "predictable agency workload of requests," exceptional circumstances will not lie "unless the agency [further] demonstrates reasonable progress in reducing its backlog of pending requests." 5 U.S.C. § 552(a)(6)(C)(ii).

III. DISCUSSION

The Court's discussion here proceeds in three parts: first, the Court shall explain why the FDA has failed to establish that the DIDP is overwhelmed by burdens vastly in excess of those anticipated by Congress; second, the Court shall explain why the FDA has failed to establish that the DIDP has made reasonable progress in reducing its backlog of requests; and, third, the Court shall explain why the FDA has failed to establish that its existing resources are inadequate to address its current workload. These three considerations preclude a finding that the FDA faces "exceptional circumstances" in the instant case. The Court declines to reach the parties' remaining arguments.

Before proceeding, an observation concerning the posture of the present motion is in order. Less than two-and-a-half years ago this Court had the opportunity to examine whether the FDA—and, specifically, the DIDP—faced "exceptional circumstances" in terms of its workload of requests and whether it had demonstrated "due diligence" and "reasonable progress" in reducing its backlog of requests. *See Gov't Accountability Project v. U.S. Dep't of Health & Human Servs.*, 568 F. Supp. 2d 55 (D.D.C. 2008). On that occasion, presented with strikingly similar evidence as that now relied upon by the FDA, the Court denied a comparable request for a stay of those proceedings, finding that the FDA had failed to demonstrate that the DIDP was experiencing "exceptional circumstances," had exercised "due diligence" in responding to requests, or had made "reasonable progress" in reducing its backlog of requests. *See generally id.* Therefore, in the instant case, the parties have appropriately paid particular attention to how the workload now facing the DIDP and its progress in reducing its backlog have changed in the

past two years, and whether such changes warrant a different conclusion at this time. Where appropriate, the Court shall do the same.[5]

A. The FDA Has Failed To Establish That It Is Overwhelmed By Burdens Vastly In Excess Of Those Anticipated By Congress

The FDA has failed to establish that it is overwhelmed "with [a] volume of requests . . . vastly in excess of that anticipated by Congress." *Open Am.*, 547 F.2d at 616. Indeed, the record created by the parties suggests, if anything, that the burdens facing the FDA—and, in particular, the DIDP—have declined in recent history. According to the FDA's own figures, the DIDP received 5,310 requests in 2003, 5,156 in 2004, 4,050 in 2005, 3,335 in 2006, 2,888 in 2007, 2,260 in 2008, and 1,756 in 2009. Sager Decl. ¶ 22.[6] The FDA concedes that the numbers in the most recent years have trended downward, but maintains that the numbers do not reflect the complexity or size of the requests received or "the level of effort required to respond to each individual request." *Id.* ¶ 22. More specifically, the FDA seeks to discount this downward trend by suggesting that, as a result of its ongoing efforts to post documents of public interest on its website, the DIDP no longer sees the same number of requests for common, easy-to-locate records and instead faces a higher percentage of more complex, time-consuming requests. *Id.*[7]

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[5] The FDA suggests that "recent data" that was not available at the time the Court last addressed the issue have persuaded two other courts in this Circuit to grant the FDA's request for a stay of proceedings in unpublished decisions. In each instance, the district court reached its decision without providing any discussion of its underlying reasoning and, therefore, neither authority is persuasive. *See Mehri & Skalet v. U.S. Food & Drug Admin.*, No. 09 Civ. 01898 (RJL); *Viropharma Inc. v. Dep't of Health & Human Servs.*, No. 08 Civ. 02189 (PLF).

[6] The statistical information submitted to the Court concerning the DIDP's workload extends through the end of 2009. Sager Decl. ¶ 22.

[7] In a similar vein, the FDA avers that the nature of the mission of the CDER entails that much of the information reviewed by the DIDP—for example, medical records and personal

The Court is not insensitive to the fact that the DIDP frequently processes large and complex FOIA requests, and this is indeed a relevant consideration in assessing whether the FDA has met its burden of establishing "exceptional circumstances." Nevertheless, the FDA's arguments fall short of evidencing that incoming requests have, on average, become significantly and unexpectedly more complex as of late. While the FDA's sworn declarations aver in blanket and rather unilluminating terms that the "level of effort required to respond to each individual request has increased on average," *id.*, there is simply insufficient evidence in the record to draw any concrete and meaningful conclusions as to the composition of the DIDP's workload today in comparison to years past, at least in terms of complexity. In any event, even crediting the FDA's contention that the ratio of complex requests to simple requests has increased over time, that does not necessarily mean that the DIDP now faces, on the whole, a more complex workload where the volume of incoming requests has simultaneously declined over time. Simply by way of example, according to the FDA's own figures, the number of requests received by the DIDP dropped from 5,310 in 2003 to 1,756 in 2009, a decline of 3,554—or 66.9%. Yet there is insufficient evidence in the record that would allow this Court to draw a meaningful conclusion as to whether the DIDP's workload has, on the whole, increased in complexity with sufficient magnitude to offset the downward trend in overall requests.

Simply put, absent significantly more detail in the record, the Court cannot draw any meaningful conclusions from the FDA's blanket descriptions and considers this sufficient to

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information, trade secret and confidential commercial information, and deliberative process information—is exempt from public disclosure, requiring the DIDP to exercise particular care when it reviews records prior to release. Sager Decl. ¶ 17. While understandable, this state of affairs is hardly unexpected or unusual.

conclude that the FDA has failed to carry its burden of establishing that it is overwhelmed by a large and unanticipated number of requests. Nevertheless, the FDA does not rest its case on the volume and complexity of requests alone, suggesting that "extraordinary circumstances" may also be found in the instant case because the DIDP must (a) respond to requests from Congress and other governmental entities, (b) respond to requests required by FOIA lawsuits and subpoenas, and (c) comply with ongoing disclosure obligations in legislative enactments. *See generally* Def.'s Reply at 6-7.[8] The Court considers each argument in turn.

First, the FDA stresses that the DIDP's workload has increased in recent history by virtue of requests from Congress, agencies, and foreign, state, and local governments. Sager Decl. ¶ 19. The FDA suggests that due to the "high-profile nature and public importance of many of these requests," the DIDP generally gives these often complex and time-intensive requests priority above other requests. *Id.* The FDA again fails to provide a sufficiently particularized showing as to the burdens involved in responding to such requests. As an initial matter, the FDA never specifically identifies any such request or attempts to articulate the number, frequency, or scope of such requests over time, resorting instead to such vague and generalized assertions that it has received "multiple" or "many" requests. *Id.* Moreover, while the FDA avers that such requests "required the full-time attention of up to five DIDP employees" in 2009, it makes no attempt to compare these figures with those faced in previous years. *Id.* In fact, the FDA concedes that these types of requests have been "[a] huge part of DIDP's workload since 2004," *id.,* which suggests, if anything, that they are more a part of the DIDP's predictable workload than the

[8] Strictly speaking, the FDA rests on other arguments here that are addressed elsewhere in this opinion—including the DIDP's progress in reducing its backlog and the complexity of incoming requests. *See generally* Def.'s Reply at 6-7.

function of an unanticipated deluge of requests. In short, these requests appear to be the norm and, indeed, are strikingly similar to the arguments considered, and rejected, by this Court two years ago. Accordingly, even assuming that this aspect of the DIDP's workload was once unpredictable or unforeseen, it now appears to be routine.

Second, the FDA suggests—in passing and without much elaboration—that document productions made in connection with FOIA-related lawsuits and subpoenas comprise part of the DIDP's present workload. Sager Decl. ¶¶ 16, 21. The FDA, however, offers only a single example—a court order requiring the production of documents that required a total of 238 hours of search and review time over an unspecified period that may or may not consume additional time and resources this year. *Id.* ¶ 16. Few, if any, conclusions can be drawn from such a limited factual showing. Furthermore, here as well, the FDA neglects to compare the DIDP's present workload with past levels in such a way that would permit the Court to draw any broader conclusions about the DIDP's workload as it has developed over time.

Third, the FDA argues that its workload has increased with new obligations under legislative enactments—namely, the Food and Drug Administration Amendments Act of 2007 (the "FDAAA"), Pub. L. No. 110-85. The FDA contends that the disclosure requirements imposed upon it by the FDAAA have proved to be more resource-intensive than originally expected, and "[a]lthough DIDP planned to have put in place procedures to meet its obligations . . . within the first part of 2008, these efforts occupied significant staff time throughout 2008 and 2009." Sager Decl. ¶ 20. While the FDA avers that these disclosure requirements have occupied significant staff time in prior years, it is unclear from the record how much staff time has been allocated. *Id.* Nor is it clear whether contemporaneous increases in the DIDP's staff levels may

have offset or ameliorated these "new" burdens. *See infra* Part III.C. More to the point, the FDA concedes that it has largely resolved many of the implementation issues associated with FDAAA-related disclosure obligations, and yet it makes no attempt to project what efforts will be required throughout the duration of the requested stay period—which would extend well into the present year—and instead rests merely on a vaguely defined set of responsibilities that must be met "on an ongoing basis." Sager Decl. ¶ 20. For all these reasons, while the Court does not doubt that "newly" imposed statutory obligations may be a valid consideration in determining whether a stay is appropriate, the FDA has failed to provide this Court with sufficient record support to conclude that the enactment of the FDAAA has resulted in an unmanageable deluge of unanticipated requests.

For the foregoing reasons, the Court concludes that the FDA has not carried its burden of showing that it faces a workload unanticipated by Congress. Indeed, the FDA's own figures suggest that the volume of requests submitted to the DIDP has actually decreased—and decreased substantially—in the past six years. At best, the FDA has provided conceivable but ultimately unproven bases for concluding that the DIDP's workload has not declined as substantially as these numbers would suggest; however, the FDA simply has not carried its burden of demonstrating that it presently faces the sort of overwhelming and substantial burden that would justify a finding of "exceptional circumstances." *Open Am.*, 547 F.2d at 616.

B. The FDA Has Failed To Establish That The DIDP Has Made "Reasonable Progress" In Reducing Its Backlog of Pending Requests

Where, as here, an agency can show no more than a "predictable agency workload of requests," exceptional circumstances will not lie "unless the agency [further] demonstrates reasonable progress in reducing its backlog of pending requests." 5 U.S.C. § 552(a)(6)(C)(ii);

see also Bloomberg, L.P. v. U.S. Food & Drug Admin., 500 F. Supp. 2d 371, 375 (S.D.N.Y. 2007) ("If an agency's delay is the result of an expected workload of requests, the agency must demonstrate reasonable progress in reducing its backlog of pending requests.") (internal quotation marks omitted). The FDA contends that the DIDP has taken a two-pronged approach to reducing its admittedly rather substantial backlog of FOIA requests: first, the DIDP has taken steps to voluntarily make certain information available to the public without the need to resort to FOIA; and, second, the DIDP has engaged in various efforts to process pending and incoming requests "more efficiently." Sager Decl. ¶ 23.[9] The FDA places particular emphasis on the fact that the DIDP's backlog has decreased over the six-year period extending from 2003 to 2009—from 6,672 at year-end 2003 to 1,971 at year-end 2009. *Id.* ¶ 22.

Two years ago, this Court rejected nearly identical arguments, finding that the contemporaneous overall downward trend in incoming requests prevented the Court from concluding that the decrease in the DIDP's backlog was attributable to the FDA's affirmative efforts. *See Gov't Accountability Project*, 568 F. Supp. 2d at 63 (reasoning that a 54% decrease in incoming requests raised questions about the origins of a 50% decrease in the DIDP's backlog). The FDA has offered no reason to reach a different conclusion now. Here too, despite its assertion that "[t]he current data provides [sic] a more complete picture" than was available

[9] More specifically, the FDA avers that, in recent years, it has: (a) as a matter of regular practice, posted documents of interest on its publicly accessible website; (b) engaged in customer education and outreach efforts with large-volume requesters in order to reduce both the overall number and scope of requests; (c) consolidated three systems for tracking FOIA requests into a single agency-wide system; (d) transitioned to a new electronic information management system; (e) implemented organizational changes to increase the efficiency of its operations; (f) continually supplemented its staff with additional members; and (g) consistently processed FOIA requests at a greater rate than with which they are received. Sager Decl. ¶¶ 23-32.

two years ago, Def.'s Reply at 10, the FDA offers little beyond its own speculation that there is a causal connection between its efforts and the downward trend in incoming requests. Notably, despite the fact that the FDA rests in large part on its self-described "proactive" efforts to make certain information available to the public without the need to resort to FOIA, the FDA concedes that it cannot quantify the relationship between such efforts and the downward trend in incoming requests and—in lieu of attempting to provide some concrete basis for concluding that such a correlation exists—essentially offers its *ipse dixit* that "a correlation exists." Sager Decl. ¶ 26. Similarly, the FDA makes no meaningful attempt to establish an affirmative link between broader changes in its processes and procedures and the reduction in the DIDP's backlog—let alone provide the Court with a quantifiable means to evaluate and assess the claimed link. Simply put, based upon the record the FDA has created, the Court cannot determine whether the decrease in the DIDP's backlog is attributable to the measures identified by the FDA or rather the contemporaneous and substantial downward trend in incoming requests.

Nor does the record support the inference that the DIDP has been reducing its backlog of pending requests at a significantly more rapid rate than the contemporaneous decline in the number of incoming requests. According to the FDA, over the six-year period extending from 2003 through 2009, the DIDP decreased its backlog of pending requests at a faster rate (71%) than the volume of incoming requests decreased (67%)—a difference of 4%.[10] Sager Decl. ¶ 22. The Court cannot conclude that the FDA has met its burden of demonstrating "reasonable

[10] While the precise rate is not particularly important, the difference between the decline in the DIDP's backlog and the downward trend in incoming requests is actually slightly less than the 4% cited by the FDA. In calculating the 4% figure, the FDA relies on the peak of the backlog in 2003 rather than year-end numbers, while it uses year-end numbers to calculate the downward trend in requests. Using the same benchmark, the difference would be around 3.5%.

progress" on the basis that the DIDP is reducing its backlog at what is, at best, a marginally more rapid rate than the downward trend in the number of incoming requests. *Cf. Bloomberg L.P.*, 500 F. Supp. 2d at 376 (finding that a 37% decrease in the agency's backlog was roughly equivalent to the 33.3% or greater decline in incoming FOIA requests).

Meanwhile, Plaintiffs correctly point out that between 2008 and 2009—the most recent period for which the FDA has supplied data—the number of requests processed by the DIDP actually dropped from 3,807 to 2,718, a decline of 28.6%. Sager Decl. ¶ 22. The FDA questions the validity of single-year statistics and counters that Plaintiffs' argument fails to account for the impact of the various "proactive" measures it has identified. However, even expanding the inquiry to the last four years for which the Court has data—the period which the FDA suggests supports a correlation between its self-described "proactive" efforts and the reduction in the DIDP's workload—the record does not evidence a consistent pattern in the rate at which the agency has processed requests. Indeed, over that period, the rate at which the DIDP has processed requests has moved from -10.5% (2006 to 2007) to +8.8% (2007 to 2008) to -28.6% (2008 to 2009). *Id.* While not dispositive, these considerations further undermine the FDA's contention that its actions support a finding of "reasonable progress" in reducing the DIDP's backlog. In short, while the Court commends the FDA for the steps its has taken to meet its statutory obligations in the face of no small number of requests, the Court finds—based on the record created by the FDA—that the FDA has failed to prove that these efforts have yielded "reasonable progress" in reducing the DIDP's backlog.

C. The FDA Has Failed To Establish That Its Existing Resources Are Inadequate

Even assuming, *arguendo*, that the FDA was able to establish "reasonable progress" in reducing the DIDP's backlog of pending requests, an additional, independent factor precludes a finding of "exceptional circumstances" in this case. In order to establish that "exceptional circumstances" exist, an agency must establish that its existing resources are "inadequate to deal with [the] volume of such requests within the time limits" prescribed by FOIA. *Open Am.*, 547 F.2d at 616. In the instant case, while the FDA has failed to meet the threshold showing of a sufficiently pronounced increase in the DIDP's workload such that would constitute exceptional circumstances, it has similarly failed to establish that its resources are inadequate to address the volume and complexity of requests faced. Indeed, according to the FDA's own submissions, the DIDP's staff nearly doubled from 2002 to 2009—from 18 full-time employees in 2002 to 33 full-time employees and 2 full-time contractors in 2009. Sager Decl. ¶ 32.[11] Indeed, in the two years that have intervened since the Court last addressed the workload and resources of the DIDP, the DIDP has added approximately 5 new staff members, an increase of over 16%. *See Gov't Accountability Project*, 568 F. Supp. 2d at 62 (noting that, as of 2008, the DIDP had a total of 30 staff members—28 full-time employees and 2 full-time contractors). Moreover, at the time it filed its moving papers in this action, the FDA intended to augment its staff with an additional 4 full-time employees. Sager Decl. ¶ 32. The FDA cautions, not without some force, that an increase in staff levels may not necessarily carry with it an instant

[11] The precise number of DIDP staff members in place at year-end of 2009 is not entirely clear from the record. At one point, the FDA's sworn declarations suggest that there were 31 employees and 2 contractors; elsewhere, the numbers are listed as 33 employees and 2 contractors. The difference is ultimately immaterial, as both figures represent an increase in the DIDP's staff levels in the time since the Court last had the opportunity to address the issue.

reduction in workload. However, at best, this counsels in favor of exercising some restraint in drawing an adverse conclusion based upon the increase in the FDA's resources over time. It does not suffice to discharge the FDA's burden of establishing that its "existing resources are inadequate." *Open Am.*, 547 F.2d at 616. *Compare Gov't Accountability Project*, 568 F. Supp. 2d at 62 (denying stay where agency's affidavits failed to "describe a situation in which . . . staffing levels have dropped precipitously at the same time the agency has faced an increased workload"), *with Elec. Frontier Found. v. Dep't of Justice*, 517 F. Supp. 2d 111, 115-16 (D.D.C. 2007) (granting stay where agency was 115 positions under staffing level and government hiring freeze made future hiring unlikely).

In sum, the record simply does not allow the Court to conclude that "exceptional circumstances" exist in this case. Based on the record created by the parties, there may very well be reasons to doubt that the situation faced by the DIDP has improved quite as much as the downward trend in incoming requests would suggest; at the same time, there is no basis to conclude that either the number and complexity of requests has increased with sufficient magnitude to offset this downward trend or that the DIDP lacks the resources sufficient to discharge its statutory responsibilities.

IV. CONCLUSION

For the foregoing reasons, the Court shall DENY the FDA's [7] Motion for a Stay. The Court declines to reach the remaining arguments raised by the parties. Although mindful of the substantial backlog of requests the DIDP presently faces, the FDA has already had well over a year to process the Outstanding Requests and has represented that it is capable of completing production within approximately two weeks to a month after commencing its review.

Accordingly, the Court shall require the FDA to (a) begin processing Plaintiffs' FOIA requests immediately, (b) promptly produce any responsive documents on a rolling basis, and (c) complete its production on or before March 4, 2011. An appropriate Order accompanies this Memorandum Opinion.

Date: February 24, 2011

/s/
COLLEEN KOLLAR-KOTELLY
United States District Judge